

**NHGRI IRB Protocol Checklist: One copy of this checklist must accompany all submissions.**

**I. NEW PROTOCOL FOR IRB REVIEW (original + 25 stapled copies)**

- ☐ Form 1195 signed by PI, Accountable Investigator, Branch Chief.
- ☐ NHGRI Human Subjects Research Protocol Template, including item 9, a plan for monitoring adverse events.
- ☐ Gender and Ethnicity Tracking Form (complete Section A; use “unknown” if specific numbers are not being targeted) or Inclusion Enrollment Form and Target/Planned Enrollment Table.
- ☐ Appendices including questionnaires, educational materials, investigator’s brochure, etc.
- ☐ Participant recruitment materials.
- ☐ Consent form(s).
- ☐ Diskette or e-mail containing consent form(s). Please do not use Word Perfect.
- ☐ SRC correspondence including SRC review, PI response (if any).

**II. CONTINUING REVIEWS YEARLY (Protocol Number \_\_\_\_\_) (original + 25 stapled copies)**

- ☐ Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- ☐ Table of Contents indicating a page for each of the additional continuing review elements listed below.
- ☐ Cover memo addressing:
  - a) A concise statement regarding protocol progress to date and key findings.
  - b) Address any “Yes” responses to questions on 1195-1 (i.e., slower than expected accrual, complications/side effects, withdrawals, etc).
  - c) Whether there will be continuing accrual of research participants.
  - d) Reason(s) for continuing the study.
  - e) Any amendments made within the last year.
  - f) Currently proposed changes in protocol or consent form.
  - g) Any changes in the protocol that would require a new consent form to be signed.
  - h) Any study publications (if none, please state “NONE”).
- ☐ Gender and Ethnicity Tracking Form (complete Sections A, B, and C; use “unknown” in Section C if specific numbers are not being targeted) or Inclusion Enrollment Form and Target/Planned Enrollment Table
- ☐ Amended pages, with the additions and ~~deletions~~, so noted.
- ☐ Revised version of protocol, including a plan for monitoring adverse events (Section 9).
- ☐ Current consent form, revised, if applicable.
- ☐ A copy of IRB stipulations/recommendations from previous year.
- ☐ Diskette or e-mail containing consent form IF changes to consent form are involved. Please do not use Word Perfect.

**III. RENEWAL AFTER THREE YEARS (Protocol Number \_\_\_\_\_) (original + 25 stapled copies)**

- ☐ Form 1195-1 signed by PI, Accountable Investigator, Branch Chief
- ☐ Table of Contents indicating a page for each of the additional continuing review elements listed below.
- ☐ Cover memo addressing any amendments made within the last year, any currently proposed changes in protocol or consent, any changes in the protocol that would require a new consent form to be signed, and any study publications.
- ☐ Gender and Ethnicity Tracking Form (include target numbers in addition to accrued and cumulative numbers; use “unknown” if specific numbers are not being targeted) or Inclusion Enrollment Form and Target/Planned Enrollment Table.
- ☐ Protocol – Rewritten according to template to address:
  - a) A concise statement regarding protocol progress to date and key findings.

- b) Address any “Yes” responses to questions on 1195-1 (i.e., slower than expected accrual, Complications/side effects, withdrawals, etc).
- c) Changes in the field that have an impact on future direction, including publications.
- d) Include in Item 9 a plan for monitoring adverse events.
- e) Reason(s) for continuing the study and description of new approaches.
- ☐ Amended pages, with the additions and ~~deletions~~, so noted.
- ☐ Revised or current consent form, if applicable.
- ☐ SRC correspondence including SRC review, PI response (if any).
- ☐ A copy of IRB stipulations/recommendations from previous year.
- ☐ Diskette or e-mail containing consent form IF changes to consent form are involved. Please do not use Word Perfect.

**IV. REVISED PROTOCOL FOR FULL IRB REVIEW (original + 25 stapled copies)**

- ☐ Cover memo responding point-by-point to critique.
- ☐ Revised pages of protocol and consent, with the additions and ~~deletions~~, so noted.
- ☐ Copy of IRB Meeting Minute Stipulations.
- ☐ Clean copies of entire revised protocol and consent.
- ☐ Diskette or e-mail containing consent form. Please do not use Word Perfect.

**V. RESPONSES TO STIPULATIONS FOR CONDITIONALLY APPROVED PROTOCOLS (original + 6 stapled copies if returned to a IRB Subcommittee; original + 3 stapled copies if returned to NHGRI IRB Chair)**

- ☐ Cover memo responding point-by-point to stipulations.
- ☐ Revised pages of protocol and consent, with the additions and ~~deletions~~, so noted.
- ☐ Copy of IRB Meeting Minute Stipulations.
- ☐ Clean copies of entire revised protocol and consent.
- ☐ Diskette or e-mail containing consent. Please do not use Word Perfect.

**VI. AMENDMENTS - (PROTOCOL # \_\_\_\_\_). Call Sara Hull (301-435-8712) to determine type.**

**Expedited amendments (original + 6 stapled copies)**

- ☐ Cover memo explaining changes.
- ☐ Amended pages, with the additions and ~~deletions~~, so noted.
- ☐ Complete, clean protocol and consent form.
- ☐ Diskette or e-mail containing consent form IF changes to consent are involved. Please do not use Word Perfect.

**OR**

- ☐ “Previously Collected Human Biological Materials/Data” Amendment Form.

**Full board review (original + 25 stapled copies)**

- ☐ Cover memo explaining changes.
- ☐ Amended pages, with the additions and ~~deletions~~, so noted.
- ☐ Complete, clean protocol and consent form.
- ☐ Diskette or e-mail containing consent form IF changes to consent are involved. Please do not use Word Perfect.

**VII. TERMINATIONS (Protocol Number \_\_\_\_\_): Original and 3 copies**

- ❑ Cover memo addressing key findings of the study and why the study was terminated.
- ❑ Form 1195-1 signed by PI, Accountable Investigator, Branch Chief.
- ❑ Gender and Ethnicity Tracking Form or Inclusion Enrollment Form and Target/Planned Enrollment Table
- ❑ Consent form

Materials for full IRB review must be submitted to Peggy McKoy Bldg 49, Room 4A14 by Noon on the due date, or they may be reviewed at a later meeting. (See NHGRI IRB Calendar).

***For questions regarding the checklist or submissions, please contact:***

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